

anchoring a first body tissue layer to a second body tissue layer. In a first embodiment, a sheath having a longitudinal bore therethrough is provided. The sheath has a proximal end and a distal end, the distal end is adapted for insertion through at least two body tissue layers and into a body orifice from a point exterior to the body orifice. A hollow preshaped microthin polymeric device is used with the sheath the device contains a shaft and a ballooned region located at or proximal to a distal end of the device. The device slidably engages the bore of the sheath such that the distal ends of each are proximate to one another. While they are engaged, the retention element is in a first collapsed state. A second free end of the device protrudes from the proximal end of the sheath. The device is adapted to be slid distally through the bore until at least the retention element is free of the sheath whereupon an inflation source may be applied to the device ballooning the retention element into a second expanded state.

[0011] Such an apparatus may utilize a device made wholly or partially of a polyurethane material. The sheath may be longitudinally splittable into two or more sections along a longitudinal separation line. Other embodiments may use a non-splittable sheath having a slot or groove at a distal end for the capture of the retention element therein. A retainer for affixing to a portion of the shaft protruding from the body to retain the apparatus in position may also be provided.

[0012] In another embodiment, an apparatus for insertion into a body orifice for anchoring a first body tissue layer to a second body tissue layer would have a hollow, collapsible, microthin polymeric shaft affixed to a noncollapsible tip at a distal end of the polymeric shaft. A preformed balloonable distention formed in a discrete region of the shaft proximal to the noncollapsible tip would be adapted to anchor against one of the body tissue layers within the body orifice. A rod may be attached at one end to the tip, allowed to extend along the shaft and terminate at a second end near a proximal end of the device. The rod would be adapted to transfer movement from the second end to the first end so as to effect a movement in the tip. The rod may be wholly or partially located internal to the shaft, external to the shaft, and/or within the shaft wall. This apparatus may have a proximally facing flattened surface on the balloonable distention located substantially normal to a longitudinal axis through the shaft.

[0013] A method for anchoring a first body tissue layer to a second body tissue layer would encompass the following steps: inserting a distal end of a longitudinally splittable sheath having a throughbore into a body through at least a first body tissue layer, a second body tissue layer, and into a body cavity, leaving a proximal end of the sheath protruding externally from the body; advancing a hollow preshaped microthin polymeric device having a shaft with a ballooned region integrated into a distal end of the shaft along the throughbore until the retention element protrudes from the distal end of the sheath; ballooning the retention member by inflating the member so that it expands from a first deflated condition to a second inflated condition; withdrawing the sheath from the body and sliding it free from the polymeric shaft at a proximal end of the shaft; and pulling the first and second body tissue layers one toward the other by applying a tensile force to the shaft so that the retention member contacts and draws one body tissue layer toward the other body tissue layer.

[0014] Another method may encompass the steps of perforating the first and second body tissue layers to create a stoma extending from a first region to a second region within a body orifice; advancing a hollow preshaped microthin polymeric device having a shaft with a ballooned region integrated into a distal end of the shaft into the body orifice by manipulating a rod attached at the distal end and extending to a proximal

end until the ballooned region is situated; ballooning the retention member by inflating the member so that it expands from a first deflated condition to a second inflated condition; and pulling the first and second body tissue layers one toward the other by applying a tensile force to the shaft so that the retention member contacts and draws one body tissue layer toward the other body tissue layer.

[0015] Additional steps may include by itself or in any combination, the following: tying off an end of the shaft which protrudes externally from the stoma; engaging an end of the shaft which protrudes externally from the stoma with a thin retainer adapted to secure the protruding shaft proximal to the perforation; and/or bandaging the protruding shaft and retainer.

[0016] The apparatus and methods described herein would be suitable for use in performing a gastropexy procedure wherein one of the body tissue layers comprises the abdominal wall and the other layer comprises the stomach. Other objects, advantages and applications of the present invention will be made clear by the following detailed description of a preferred embodiment of the invention and the accompanying drawings wherein reference numerals refer to like or equivalent structures.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] FIG. 1 depicts an illustrative view of one embodiment of the present inventive kit for use in a percutaneous gastrointestinal anchoring procedure.

[0018] FIG. 2 depicts an illustrative view of the anchor of the FIG. 1 kit in greater detail.

[0019] FIG. 3 depicts an illustrative view of the introducer of the FIG. 1 kit in greater detail.

[0020] FIG. 4 depicts an illustrative view of an alternative embodiment of the FIG. 3 introducer.

[0021] FIG. 5 depicts an illustrative view of the guide of the FIG. 1 kit in greater detail.

[0022] FIG. 6 depicts an illustrative view of an alternative embodiment of the FIG. 5 guide.

[0023] FIG. 7 depicts an illustrative view of the retainer of the FIG. 1 kit in greater detail.

[0024] FIG. 8 depicts an illustrative view of an alternative embodiment of the FIG. 7 retainer.

[0025] FIG. 9 depicts an illustrative view of the introducer of the FIG. 1 kit at a point in time when the anchor is in place in the procedure.

DETAILED DESCRIPTION OF THE PRESENT INVENTION

[0026] Reference will now be made in detail to embodiments of the invention, one or more examples of which are illustrated in the figures. The embodiments are provided by way of explanation of the invention, and not meant as a limitation of the invention. For example, features illustrated or described as part of one embodiment may be used with another embodiment to yield still a different embodiment. It is intended that the invention include these and other modifications as come within the scope and spirit of the invention.

[0027] In response to the foregoing challenges that have been experienced by those of skill in the art, the present invention is directed toward a kit for performing percutaneous gastrointestinal anchoring of the anterior wall of the stomach to an anterior wall of the abdomen. Components within such a kit would enable the incising of an exterior surface of a living body, the introduction of an anchoring device into the incision from the exterior surface through intervening tissue layers and into the stomach cavity or gastric lumen. More-